4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-0775]

Content of Premarket Submissions for Device Software Functions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Content of Premarket Submissions for Device Software Functions." This guidance document is intended to provide information regarding the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of safety and effectiveness of device software functions, which are functions that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This document replaces FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, and updates FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-D-0775 for "Content of Premarket Submissions for Device Software Functions." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Content of Premarket Submissions for Device Software Functions" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Brendan O'Leary, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5530, Silver Spring, MD 20993-0002, 301-796-6898; Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911; Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993-0002, 301-796-3400; or John Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130 HFG-3, Silver Spring, MD 20993-0002, 301-796-8941.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this guidance is to describe FDA's thinking on the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions. This thinking recognizes changes to the FD&C Act made by the 21st Century Cures Act (Cures Act), which amended section 520 of the FD&C Act (21 U.S.C. 360j) and excludes certain software functions from the device definition. It also considers the rapidly evolving nature of digital health and recent FDA recognized consensus standards related to software.

The recommendations in this guidance are intended to facilitate FDA's premarket review. This guidance describes information that would be typically generated and documented during software development, verification, and design validation. The least burdensome approach was applied to identify the minimum amount of information that, based on our experience, would generally be needed to support a premarket submission for a device that uses software. During

premarket review, FDA may request additional information that is needed to evaluate the submission.

This document replaces FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, and updates FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions.

A notice of availability of the draft guidance appeared in the *Federal Register* of November 4, 2021 (86 FR 60838). FDA considered comments received and revised the guidance as appropriate in response to the comments, including edits to clarify FDA's risk-based approach to determining a device's Documentation Level (including an expanded Appendix of examples that illustrate application of the Documentation Level risk-based approach) as well as edits to clarify the recommended documentation that should be included within a premarket submission. The guidance also clarifies that the recommendations generally apply to the device constituent part of a combination product when the device constituent part includes a device software function, including combination products assigned to FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) regulated under drug or biological product market submission types. FDA also edited the document to further clarify the recommended utilization of FDA-recognized versions of consensus standards, where appropriate, within a premarket submission.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Content of Premarket Submissions for Device Software Functions." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics. Persons unable to download an electronic copy of "Content of Premarket Submissions for Device Software Functions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00000337 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
860, subpart D	De Novo classification process	0910-0844
601; Form FDA 356h	Biologics License; Application to Market a New or Abbreviated New Drug or Biologic for Human Use--Form FDA 356h	0910-0338
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"	Q-submissions	0910-0756

800, 801, and 809	Medical Device Labeling Regulations	0910-0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073

Dated: June 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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